

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY


(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

REC'D 27 OCT 2005

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Applicant's or agent's file reference P14409PCDK	FOR FURTHER ACTION		See Form PCT/IPEA/416
International application No. PCT/DK2004/000499	International filing date (day/month/year) 09.07.2004	Priority date (day/month/year) 11.07.2003	
International Patent Classification (IPC) or national classification and IPC A61M15/00, G06M3/12, G06M1/08, E05B15/00, E05C17/18			
Applicant BANG & OLUFSEN MEDICOM A/S et al.			
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 9 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p style="margin-left: 20px;">a. <input checked="" type="checkbox"/> sent to the applicant and to the International Bureau) a total of 1 sheets, as follows:</p> <p style="margin-left: 40px;"><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p style="margin-left: 40px;"><input checked="" type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in Item 4 of Box No. I and the Supplemental Box.</p> <p style="margin-left: 20px;">b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>			
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the opinion</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input checked="" type="checkbox"/> Box No. VI Certain documents cited</p> <p><input checked="" type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input checked="" type="checkbox"/> Box No. VIII Certain observations on the international application</p>			
Date of submission of the demand 11.05.2005		Date of completion of this report 26.10.2005	
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Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4)
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):*

Description, Pages

1-13 as originally filed

Claims, Numbers

4-12 as originally filed

1-3 received on 27.05.2005 with letter of 25.05.2005

Drawings, Sheets

1/5-5/5 as originally filed

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing (*specify*):
- ☐ any table(s) related to sequence listing (*specify*):

4. ☒ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages
- ☒ the claims, Nos. 1-3
- ☐ the drawings, sheets/figs
- ☐ the sequence listing (*specify*):
- ☐ any table(s) related to sequence listing (*specify*):

* If item 4 applies, some or all of these sheets may be marked "superseded."

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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	4,5,7,8-12
	No: Claims	1,2,3,6
Inventive step (IS)	Yes: Claims	9-12
	No: Claims	1-8
Industrial applicability (IA)	Yes: Claims	1-12
	No: Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Box No. VI Certain documents cited

1. Certain published documents (Rule 70.10)

and / or

2. Non-written disclosures (Rule 70.9)

see separate sheet

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item I

Basis of the report

This report has been established as if amended claims 1 to 3 filed with the letter dated 25-05-2005 had not been made, since they have been considered to go beyond the disclosure as filed. Indeed:

Amended claim 1 now reads that the retaining members allow the engagement section of the leg member to move **unhindered** in a first direction **on the first track** towards the sliding guide but block movement in the opposite second direction. Nevertheless, it is clear from the description as originally filed (see page 4, lines 1 to 30, and figure 1) that the device of the present invention is provided with a first track where the engagement section of the leg member can travel unhindered in one direction, whereby said engagement section will abut the side of the second track made up of one or more retaining members due to the biasing force applied to the engagement section. Once the engagement section reaches the end of said first track, the biasing force will push the engagement section onto the second track. The engagement section will thus move in a second direction **on the second track towards the sliding guide**, thereby passing the one or more retaining members. Consequently, there is no clear and unambiguous basis in the application as filed for retaining members configured to allow the engagement section of the leg member to move unhindered in a first direction **on the first track towards the sliding guide** as presently defined in amended claim 1.

Amended claims 1 to 3 filed with the letter dated 25-05-2005 introduce therefore subject-matter which extends beyond the content of the application as filed, contrary to Article 34(2)(b) PCT. Consequently, this report is based on claims 1 to 12 as originally filed.

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. The following documents are referred to in this communication:
D1: FR-A-2 169 664 D2: FR-A-2 373 658 D3: CH-A-267 906
D4: FR-A-2 288 844 D5: US-A-2002/157666 D6: WO-A-2004/041334
D7: US-A-2 129 412

 **The following remarks have to be considered in the light of the objections given**

under Re Item VIII below !!!

2 INDEPENDENT CLAIM 1

- 2.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT. The document **D1** discloses (the references in parenthesis applying to this document) a mechanical return blocking device ("dispositif d'écartement" shown in fig.1) comprising:
- a first part ("bras 1") wherein parallel to a longitudinal axis at least one set of tracks comprising a first track ("guidage 11") and a second track ("guidage 9") is provided, the second track ("guidage 9") comprising one or more retaining members (provided by the "pentes d'attaque 12" and "saillies d'arrêt 8") and a sliding guide ("surface inclinée 10") arranged at one end of the second track ("guidage 9");
 - a second cooperating part ("bras 2") wherein a leg member ("levier d'arrêt 3") comprising an engagement section ("dispositif d'arrêt 5") for engagement with the tracks provided on the first part ("bras 1") is provided, said leg member ("levier d'arrêt 3") being biased towards the first part (by the "ressort 17") and said engagement section ("dispositif d'arrêt 5") being adapted to travel in the direction of the longitudinal axis;
 - wherein said one or more retaining members are configured to allow the engagement section ("dispositif d'arrêt 5") of the leg member ("levier d'arrêt 3") to move unhindered in a first direction on said second track towards the sliding guide ("surface inclinée 10") but block movement in the opposite second direction and wherein the engagement section ("dispositif d'arrêt 5") of the leg member ("levier d'arrêt 3") can slide on the sliding guide ("surface inclinée 10"), whereby the engagement section ("dispositif d'arrêt 5") and thereby the leg member ("levier d'arrêt 3") is directed from the second track ("guidage 9") to the first track ("guidage 11").

The subject-matter of claim 1 lacks therefore novelty (Article 33(2) PCT).

- 2.2 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 lacks also novelty (Article 33(2) PCT) and/or an inventive step (Article 33(3) PCT) with regard to the disclosure of documents **D2** and **D7** (see the corresponding passages cited in the search report).

3 DEPENDENT CLAIMS 2-8

Dependent claims 2-8 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty (Article 33(2) PCT) and/or inventive step (Article 33(3) PCT).

- 3.1 The additional features of dependent claims 2, 3 and 6 are already known from **D1** so that these claims lack novelty (Article 33(2) PCT).
- **Claim 2:** each retaining member of **D1** comprises an inclined sliding surface ("pente d'attaque 12") and a step ("décrochement vers le guidage 13");
 - **Claims 3 and 6:** cf. figures.
- 3.2 In claims 4, 5, 7 and 8 slight constructional changes are defined which come within the scope of the customary practice followed by persons skilled in the art. Consequently, the subject-matter of these claims appears also to lack an inventive step (Article 33(3) PCT).

4 DEPENDENT CLAIM 9

 **The following remarks have to be considered in the light of the objections given under Re Item VIII below (see Re Item VIII, paragraph 9.2) !!!**

Document **D5**, which is considered to represent the most relevant state of the art, discloses (the references in parenthesis applying to this document) a manually operated inhalation device in which the dispensation of a medicament dose from a canister arranged in the device is activated by depressing a button or lever.

From this, the subject-matter of claim 9 differs in that the button or lever is connected to a mechanically return blocking device as claimed in independent claim 1. With such a configuration, the user will only be able to activate an event (such as a dose counting/registration) by a stroke of the button/lever such that said event intended to be activated by depressing the button/lever will reliably be carried out and/or registered at the same time, or in a synchronised manner. Therefore, play in the inhalation device and tolerances can be counteracted.

The subject-matter of claim 9 is therefore novel (Article 33(2) PCT). The problem to be solved by the present invention may be regarded as "how to counteract the play and tolerances in the inhalation. The solution to this problem proposed in claim 9 of the

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present application is considered as involving an inventive step (Article 33(3) PCT) since it cannot be derived in an obvious manner from the documents cited in the search report. The documents **D1** to **D4** and **D7** relate indeed to return blocking devices for maintaining a window, a shutter and/or a door in an open position.

- 4.1 Claims 10-12 are dependent on claim 9 and as such also meet the requirements of the PCT with respect to novelty and inventive step.
5. The subject-matter of claims 1 to 12 is considered industrially applicable since it can be made or used in any kind of industry (Article 33(4) PCT).

Re Item VI

Certain documents cited

Certain published documents

Application No Patent No	Publication date (day/month/year)	Filing date (day/month/year)	Priority date (valid claim) (day/month/year)
WO-A-2004/041334	21-05-2004	01-11-2003	11-07-2003

Re Item VII

Certain defects in the international application

6. Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents **D1** to **D7** is not mentioned in the description, nor are these documents identified therein.
7. Independent claim 1 is not in the two-part form in accordance with Rule 6.3(b) PCT, with those features known in combination from the prior art being placed in the preamble (Rule 6.3(b)(i) PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).
8. The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

Re Item VIII

Certain observations on the international application

9. Although claims 1 and 9 have been drafted as separate independent claims, they appear to relate effectively to the same subject-matter and to differ from each other only with regard to the definition of the subject-matter for which protection is sought and/or in respect of the terminology used for the features of that subject-matter. The aforementioned claims therefore lack conciseness. Moreover, lack of clarity of the claims as a whole arises, since the plurality of independent claims makes it difficult to determine the matter for which protection is sought, and places an undue burden on others seeking to establish the extent of the protection.

Hence, claims 1 and 9 do not meet the requirements of Article 6 PCT.

- 9.1 Consequently, it would have been appropriate to file an amended set of claims defining the relevant subject-matter in terms of a **single** independent claim followed by dependent claims covering features which are merely optional (Rule 6.4 PCT). **When filing amended claims the applicant should have brought at the same time the description into conformity with the amended claims** (cf. in particular the "summary of the invention" on p.3, l.12 to p.10, l.2).

- 9.2 In addition, it is pointed out that expressions like "**such as...**" used in independent claim 9 have no limiting effect on the scope of the claims; that is to say, the features following any such expression are regarded as entirely optional. For the purpose of this international preliminary report on patentability, claim 9 has nevertheless been considered as directed to:

"9. A manually operated inhalation device comprising:

- a canister arranged in the device; and
- a button or lever connected to a mechanically return blocking device according to claim 1;
- wherein the dispensation of a medicament dose from said canister arranged in the device is activated by depressing said button or lever."

For the purpose of this international preliminary report on patentability, claim 9 has therefore been considered as depending on claim 1 (Rule 6.4 PCT).

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10. Expressions like “**preferably ...**, and **still further...**” (see claim 7), and “**for example...**” (see claim 8) have no limiting effect on the scope of the claims; that is to say, the features following any such expression are regarded as entirely optional.
11. The dependency of claim 3 is not clear (Article 6 PCT). Claim 3 refers indeed to the “inclined sliding surface” firstly defined in dependent claim 2 so that claim 3 cannot be dependent on claim 1. Consequently, claim 3 has been considered as depending on claim 2.
12. Dependent claim 5 defines a blocking device wherein the first part comprising the at least one set of tracks has a **circular configuration**. Nevertheless, said at least one set of tracks is defined in independent claim 1 as being **parallel to a longitudinal axis**. Consequently, the embodiment of the invention as defined in claim 5 does not appear to fall within the scope of independent claim 1. This inconsistency between the claims leads to doubt concerning the matter for which protection is sought, thereby rendering the claims unclear (Article 6 PCT).

CLAIMS

1. A mechanical return blocking device comprising two cooperating and mutually displaceable part :

5 - a first part wherein parallel to a longitudinal axis at least one set of tracks comprising a first track and a second track is provided, and that the second track comprises one or more retaining members and a sliding guide arranged at one end of the second track;

10 - a second cooperating part wherein a leg member comprising an engagement section for engagement with the tracks provided on the first part is provided, and that said leg member is biased towards the first part and that the engagement section is adapted to travel in the direction of the longitudinal axis;

15 and further that the retaining members allows the engagement section of the leg member to move unhindered in a first direction on said first track towards the sliding guide but blocks movement in the opposite second direction and that the engagement section of the leg member slides on the sliding guide, whereby the engagement section and thereby the leg member is directed from the second track to the first track.

20 2. A blocking device according to claim 1, characterised in that each retaining member comprises an inclined sliding surface having a predetermined length along which the engagement section will slide, and a step in the shape of a surface arranged at a sharp angle in relation to the sliding surface, said step connecting the top of one inclined sliding surface and the bottom of the next sliding surface, such that a saw-tooth configuration is created, and such that the engagement section of the leg will be
25 retained from movement in one direction by said step.

30 3. A blocking device according to claim 1 or 2, characterised in that at least a part of a side surface facing the first track of each retaining member is arranged at a shallow angle in respect to the longitudinal axis of the device, such that the inclined sliding surface is narrowest in the end of the first travelling direction of the engagement section.